

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant(s): Allen, et al.

Application No.: 09/737,687

Filed: 12/14/2000

Title: SALICYLAMIDES AS SERINE PROTEASE
INHIBITORS

Attorney Docket No.: 218 US

Group Art Unit: 1626

Examiner: WRIGHT, S.

Assistant Commissioner for Patents
Washington, D.C. 20231Response.

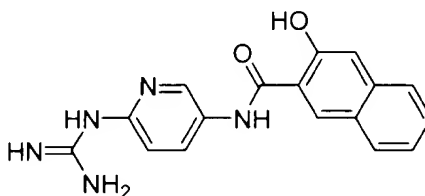
Dear Sir:

In an Office Action mailed July 30, 2001, the Examiner required the Applicants to elect one of three groups drawn to compounds of Formula I, classified in various classes and subclasses (hereinafter "Restriction Requirement I"). The Examiner further required in the Office Action that the Applicants elect a single disclosed species from within the elected group. In a Response dated October 12, 2001, the Applicants elected Group I the species found on page 66, line 8, of the specification, namely 3-hydroxy-naphthalene-2-carboxylic acid (6-guanidino-pyridin-3-yl)-amide. The Applicants traversed the election of species requirement to the extent that the Examiner intended that the non-elected species would be permanently withdrawn from consideration. Restriction Requirement I was maintained in an Office Action dated December 5, 2001, the Applicants requested reconsideration of the objection to Group I as containing non-elected subject matter in their June 24, 2002 response. All other substantive issues were resolved and Applicants thus believed the Application was put in condition for allowance. In a final Office Action dated November 20, 2002, the Examiner again maintained the objection to Claims 1-8 and 10-17 as containing non-elected subject matter. The Applicants requested that the Examiner reconsider and also filed a Petition from Requirement for Restriction under 37 C.F.R. § 1.144 (2003). The Petition was granted (hereinafter "Granted Petition").

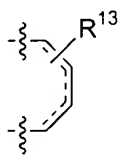
This is in response to the Requirement for Restriction mailed by the Examiner on August 4, 2003 (Restriction Requirement II). The Examiner states that the "Markush group set forth in the claims includes patentably distinct compounds (or species) within each invention" and that

"[t]his application discloses and claims a plurality of patentably distinct compounds, far too numerous to list individually." The Examiner then listed a number of species, assigning a different class and subclass for each. The Examiner did not identify which claims pertained to which of the classes and subclasses. The Examiner did require an election of species.

The Applicants elect the species found on page 66, line 8, of the specification, namely 3-hydroxy-naphthalene-2-carboxylic acid (6-guanidino-pyridin-3-yl)-amide,



where, in Formula I, R^1 , R^4 , R^8 , R^9 , R^{20} , and R^{53} are each hydrogen, R^{51} and R^{52} together form $=O$, R^5 is hydroxy, X , X^2 , X^3 , and X^4 are each carbon, X^1 is nitrogen, and R^2 and R^3 together



form and R^{13} is hydrogen. Applicants traverse Restriction Requirement II for the following reasons and reconsideration is respectfully requested.

Arguments.

Restriction Requirement.

The Applicants submit that Restriction Requirement II is improper. The particular issue here is whether the U.S.P.T.O. has the authority to compel an applicant to divide up her or his generically claimed invention pursuant to an election of species requirement. The Applicants submit that the P.T.O. does not have this authority. If, in order to comply with the Restriction Requirement, the Applicants are compelled to divide their generically claimed invention into various subgenus claims, the Applicants will not have their claims examined in the form that they believe best to define their invention. Decisions by the Patent and Trademark Office Board of Patent Appeals and its reviewing court clearly hold that a restriction requirement which compels an applicant to divide a generic claim for the purposes of excising non-elected subject matter is improper and that such a procedure amounts to a rejection.

The Applicants believe that the Examiner has intertwined elements of restriction practice with those required to support an improper Markush group rejection. The Examiner concludes that the claims contain "patentably distinct compounds (or species)... . **For this reason, restriction is required...**" (emphasis in the original). While the Examiner's terminology typically associated with improper Markush group rejections, the Examiner does not set forth any arguments to support this type of rejection. Setting forth a conclusion that the elements of an improper Markush grouping exist, without explaining why it is believed these elements are present, does not constitute a prima facie case for an improper Markush group rejection. Accordingly, the Applicants do not believe the Examiner is making an improper Markush group rejection.

The Applicants maintain that restriction practice is distinct from an improper Markush grouping rejection of a claim due to a lack of unity of invention. The proper treatment of the restriction of Markush-type claims is described in § 803.02 of the M.P.E.P. This section states in relevant part:

In applications containing claims of that nature [Markush-type], the examiner may require a provisional election of a single species prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

If the elected claims encompass more than one species, the Examiner may require that the Applicants elect a particular species for examination; however, this is a procedural tool and there is nothing found in the statutes, regulations, procedures, or case law which provides that the Applicants must amend the scope of a generic claim to excise non-elected species. This is reiterated in § 809.02(c) of the M.P.E.P.:

An examiner's action subsequent to an election of species should include a complete action on the merits of all claims readable on the elected species.

....

(B) When a generic claim is subsequently found to be allowable, and not more than a reasonable number of additional species are claimed [in different claims], treatment shall be as follows:

(1) When all claims to each of the additional species are embraced by an allowable generic claim as provided by 37 CFR 1.141, applicant must be advised of the allowable generic claim and that claims drawn to the non-elected species are no longer withdrawn since they are fully embraced by the allowed generic claim.

(Emphasis added.) The Applicants point out the "a reasonable number" of species refers to those *specifically* enumerated by a claim and not to the number of species embraced by the generic claim.

The proper procedure for restriction of a Markush claim is as follows. The examiner may require an applicant to elect provisionally a species for examination. If the elected species is ultimately found patentable, then examination is extended to the provisionally withdrawn subgenera. If a species is examined on the merits and found unpatentable, the Examiner then may reject any claims which read on the unpatentable species. This rejection may be overcome by amendment. Thus, the prior art search is not extended unnecessarily and the applicant's invention, as he or she contemplates it, is examined on the merits. It is clear that the Examiner has again failed to follow the USPTO procedures as set forth in § 803.02 of the M.P.E.P. As the Director of Technology Center 1600 (hereinafter "Director") pointed out in the Granted Petition, "[t]he examiner appears to consider the election of species as a restriction requirement rather than an election of species requirement." Here again, the Examiner has required that the Applicants elect a species which will then be used as a basis for a restriction requirement after which non-elected subject matter will be withdrawn from the claims.

Hence, while it is proper to withdraw non-elected subject matter *provisionally* during an examination of a species, it is improper to withdraw *permanently* from consideration all non-elected species. If, after an election and an examination on the merits, the examiner believes that the generic Markush claim contains subject matter that lacks unity of invention, then the examiner may make a rejection based on an improper Markush grouping accompanied by sufficient evidence by way of remarks to support the rejection.

The Applicants respectfully submit that the issue is not whether the Applicant's generic claims encompass independent and distinct inventions. The Applicants do not make any

assertions one way or the other in this regard. However, contrary to the Examiner's discussion of "distinct compounds (or species) within each invention" (emphasis added), it should be noted that the Applicants consider the Application to contain one invention of which there are different aspects. The Applicants contend that under standard restriction practice Markush claims are treated differently than independently claimed inventions. The Applicants direct the attention of the Examiner to § 803.02 of the M.P.E.P. which states:

A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s).

The Examiner goes on to argue that "where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103." While making no assertions about the diversity of Markush group members in the claims of this Application, the Applicants submit that § 803.02 specifically allows a Markush claim to contain members that are diverse enough that prior art making one member obvious would not make another obvious.

Even if the Examiner were asserting an improper Markush grouping rejection, the Office has not met its burden to show how an improper Markush grouping would be supported. No evidence is given for why the compounds are distinct, and are thus subject to restriction. In the August 4, 2003 Office Action, the extent of the support given by the Examiner is that "[t]he compounds encompassed by Formula 1 are so different that they would be separately classified and support separate patents." In fact, the Director concluded in the Granted Petition that the Examiner had not met the PTO's burden in Restriction Requirement I of showing that "the compounds encompassed by Formula I are so different that they would be separately classified and support separate patents." In Restriction Requirement II, the Examiner lists some species from the patent which would be categorized into different classes and subclasses. However, the Applicants observe, that two of the species that the Examiner has classified in separate classes and subclasses, namely "*N*-(4-carbamimidoyl-phenyl)-2-hydroxy-3-piperazinyl-benzamide, class 544 subclass 400; *N*-(4-carbamimidoylphenyl)-2-hydroxy-3-piperidiny-benzamide, class 546 subclass 231", differ by only one nitrogen. In the Granted Petition, the Director found that "[t]he examiner's arguments have also not shown how the elected subject matter differs significantly in

structure from the non-elected subject matter" (page 3, Granted Petition). Without making any assertions regarding whether or not species are patentably distinct, the Applicants maintain that the PTO has again failed to sustain its burden of showing how these classes and subclasses would support separate patents.

The central issue in Restriction Requirement II is that the Examiner has again imposed an improper restriction of a Markush group and has failed to follow P.T.O. procedures. The Examiner has indicated that non-elected subject matter will be withdrawn which will include the withdrawal of entire claims that are sub-genuses of the most generic Markush claim, and/or parts of individual claims. The M.P.E.P. does not allow either practice. Entire claims that are dependent on the most generic claim of the invention are allowed to contain independent and distinct inventions. The Applicants direct the Commissioner to 37 C.F.R. § 1.141 (a) (2003):

Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided that the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim. (Emphasis added.)

In Claims 2-31, the Applicants' have claimed species of the generic Claim 1. Even assuming these species claims represent independent and distinct inventions, they include all of the limitations of the generic claim from which they depend. Written in such a manner, it is entirely proper for the Application to contain species claims that may be independent and distinct.

In this Application, the Examiner's requirement to excise non-elected subject matter will inevitably result in withdrawal of subject matter from within the most generic Claim 1 as well as from within individual claims that depend from generic Claim 1. The Examiner relies on 35 U.S.C. 121 and 37 C.F.R. 1.142(b) for the authority to do this. In the August 4, 2003 Office Action on page five, the Examiner stated that all compounds "falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to non-elected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b)." Using 37 C.F.R. § 1.142(b), the Examiner carved out a subgeneric concept based on classifications, inclusive of the elected species, and withdrew the non-elected subject matter from further consideration. The Applicants respectfully point out that § 1.142(b) provides that "[c]laims to the invention or inventions not elected, if not canceled, are

nevertheless withdrawn from further consideration," (emphasis added). Please note that § 1.142(b) refers to "claims" being withdrawn. Section 1.142(b) does not provide, however, that subject matter within a generic claim may be permanently withdrawn as will inevitably occur if the invention is limited to certain classes and subclasses.

This practice of withdrawing non-elected subject matter from within a claim has been prohibited by the courts. The Applicants direct the Examiner's attention to *In re Haas*, 486 F.2d 1053 (C.C.P.A. 1973) (*Haas I*) (further proceedings at *In re Haas*, 580 F.2d 461 (C.C.P.A. 1978)). In that case, the examiner, relying on 35 U.S.C. § 121,¹ objected to two Markush claims as each being drawn to multiple patentably distinct inventions and withdrew them both from further consideration. A species claim was allowed and a "narrow Markush claim, encompassing only those reactive moieties similar to the allowed species, was suggested" (*Haas I* at 1054). The applicants were then compelled to cancel the original claims. Limiting the Applicants to certain classes and subclasses around the elected species will have the same effect. The *Haas I* court held that an objection of this sort can deny the applicant's substantive rights and amount to a rejection of those claims. The claim would never be examined on the merits, essentially denying the patentability of the invention as the applicants saw fit to claim it. In this Application, the Examiner's requirement to cancel from the generic claim all non-elected species that do not fall within the particular class and subclass of the elected species thus amounts to a rejection of the claims. This is a denial of substantive rights which is improper and appealable to the Board and its reviewing court.

The Court in *In re Weber*, 580 F.2d 455 (C.C.P.A. 1978) addressed this same situation and held that the restriction requirement was improper, stating:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the

¹ Section 121 states: "If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions".

examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

Id. at 458 (emphasis added). The *Weber* court is particularly clear that the division of a single claim by the examiner, with the non-elected subject matter being withdrawn from further consideration, is not permissible. In this Application, the Examiner has required that the Applicants divide their generic claims into multiple parts based on the PTO's classification system, denying them an examination of their invention as a whole.

Please see also *Ex parte Holt*, 214 USPQ 381 (Bd. App. 1982) (*Holt I*) (subsequent proceedings at *Ex parte Holt*, 218 U.S.P.Q. 747 (B.P.A.I. 1982) and *Rohm and Haas Company v. Robert Gottschalk, Commissioner of Patents*, 504 F.2d 259 (D.C. Cir.1974) for similar holdings.

In light of *Weber* and *Haas*, the Patent and Trademark Office revised restriction practice with respect to generically claimed inventions. The proper procedure for restricting a generic claim is delineated in M.P.E.P. § 803.02 (2001). In this regard the Appellants direct the Examiner to M.P.E.P. § 803.02, paragraphs 4 and 5, which states:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended.

(Emphasis added.) Hence, the examiner may require an applicant to elect provisionally a species for examination. If the elected species is ultimately found patentable, then the examination is extended to the provisionally withdrawn subgenera. If after reconsideration of the amended claim a second species is found unpatentable, the claim is rejected and the action is made final. Thus, the prior art search is not extended unnecessarily and the applicant's invention, as he or she contemplates it, is examined on the merits.

By limiting the scope of the invention to certain class(es) and subclass(es), the Examiner, rather than the Applicants, has defined the form in which the invention is claimed. The scope, as determined by the Examiner, will include those class(es) and subclass(es) whose compounds are "so similar as to be within the same inventive concept and reduction to practice," (page four of the August 4, 2003 Office Action). It is not clear how the Examiner, not being privy to the particular facts regarding the invention and reduction to practice, will determine how a particular species falls within the same inventive concept and reduction to practice as the elected species. The Applicants respectfully submit that the Examiner's action of defining what constitutes the Applicants' invention is improper. An applicant has a right to have each claim examined on the merits in the form she or he considers to best define her or his invention. (See 35 U.S.C. § 112, second paragraph (2002).) It is not in the Examiner's purview to define the Applicant's invention for them. The Applicants refer the Examiner to *In re Wolfrum*, 486 F.2d 588, 591 (C.C.P.A. 1973) where the court stated "[u]nder this provision of § 112, the scope of the subject matter is governed not by the examiner's conception of the 'invention' but by that 'which the applicant regards as his invention.'" *Weber* at 458 also speaks to this issue: "[a]n applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention." Here the Examiner has drafted a genus claim based on the PTO classification system and in doing so defines the invention for the Applicants. The Applicants respectfully submit that this action is clearly improper.

Finally, the Examiner gives no grounds in the August 4, 2003 Office Action upon which to support the claim of serious burden. The Examiner lists samples of "the many species" included in the claim and concludes that not restricting "would impose a serious burden in the examination of this application." However, the Examiner is not required to examine every species. The Director, on page three of the Granted Petition, acknowledged this, stating that "... M.P.E.P. 803.02 does not require all claimed species to be examined, only a reasonable number to determine whether the entire genus is allowable." In fact, the Director states that the examination would not be burdensome. The Examiner has completed a search on one subclass in each of two classes, and the Director concluded that "[s]uch a limited search, even if expanded, could not be considered burdensome to the examiner." By the Office's own admissions, it is clear that the examination of the invention as presented by the Applicants would not impose a serious burden on the Examiner.

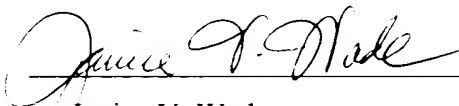
Even assuming that there is a burden on the Examiner, the Applicants respectfully submit that when there is a conflict between an applicant's statutory right to claim the subject matter of her or his invention as she or he sees fit and the Patent Office's power to regulate the workload of its Examiners, the rights of the applicant must prevail. The Applicants are mindful of the Patent Office's interest in limiting the burden of the examination in each application. The Court in *Weber* recognizing this interest stated, "[e]ven though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee." *Weber* at 458. However, the court went on to state that "... in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount." *Id.* at 458-459. The Applicants submit that their right to claim generically their invention prevails over any burden, assuming there is one, on the Patent Office.

Summary.

In view of the foregoing, the Applicants believe all claims now pending in this Application are in condition for allowance. They respectfully request reconsideration of the Restriction Requirement and issuance of a formal Notice of Allowance at an early date.

Respectfully submitted,

Date: August 26, 2003



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